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California State Senate

SENATOR
DEBORAH V. ORTIZ
SIXTH SENATORIAL DISTRICT

CHAIR,
HEALTH
SUBCOMMITTEE ON STEM CELL RESEARCH OVERSIGHT
MEMBER:
APPROPRIATIONS
JOINT LEGISLATIVE AUDIT
JOINT RULES

November 30, 2006

To: Amber Christiansen
California Department of Health Services

From: Senator Deborah V. Ortiz

Re: Comments on DHS Proposed Guidelines for Human Stem Cell Research

Submitted by Facsimile

I write to offer comments on the DHS Proposed Guidelines for Stem Cell Research by the Human Stem Cell Research Advisory Committee, aligned with and supporting what has been submitted by the Center for Genetics and Society and the Pro-Choice Alliance for Responsible Research. I worked with these two partners principally, and with many other diverse stakeholders, including members of the SB 322 Advisory Committee, over the course of the last year in the development of the ultimately successful SB 1260 (Chapter 483, Statutes of 2006). I respectfully offer the following comments for your consideration:

1. While I understand the focus on consistency with CIRM regulations discussed in your preface, the guidelines must be revised to be entirely consistent with SB 1260, rather than with conflicting or different policy that the California Institute for Regenerative Medicine (CIRM) has adopted. As you know, the provisions of SB 1260 apply to all non-CIRM funded stem cell research, which is also the domain of SB 322's charge in the creation of these guidelines. SB 1260 will go in to effect on January 1, 2007, and the guidelines need to be aligned with the impending statute that governs this area of law.

2. In accordance with the above comment, the language in Section 7 should adopt language directly from SB 1260, Chapter 2, Sections 125330-125355, rather than using language from the CIRM regulations.

3. Additionally, the guidelines must incorporate the data collection and reporting requirements of SB 1260, Chapter 2, Section 125342. Data collection is an important aspect of accountability, monitoring, enforcement, and quality. Only with good data collection and review will the state and the public be able to effectively evaluate this new science as it moves forward. This data could include the following components and should be available to the public, with exceptions for the privacy of any patient who may be personally identifiable, or for proprietary intellectual property.
    - Summaries of proposed research activities that went before the SCRO and the IRB, and whether they were approved.
    - Policies and procedures adopted by the SCRO.
    - An overview of all human stem cell research being done at the institution.
    - An overview of any failures to comply with these standards.

- A summary of results, both positive and negative, of any non-CIRM-funded research or clinical trial.
- Any significant adverse reactions in a clinical trial. A disclosure of the personal, professional, and financial interests in biotechnology or biomedical companies of the SCRO members.
- Health outcomes of oocyte donors resulting from oocyte retrieval, including adverse health reactions resulting from ovarian stimulation.
- Demographics of oocyte providers used in each stem cell line derived.

Thank you for your consideration and please contact Nicole Vazquez, Consultant to the Senate Health Committee, at (916) 651-4111 if there are any questions.

Sincerely,

DEBORAH V. ORTIZ

cc: Senator George Runner
Senator Sheila Kuehl